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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,654	04/11/2006	Cornelia Hertel	21733	7862
151	7590	12/14/2006	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/561,654

Applicant(s)

HERTEL ET AL.

Examiner

Melissa Perreira

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/14/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed on 12/20/05. It is noted, however, that applicant has not filed a certified copy of the foreign priority application 03013471.2 EPO as required by 35 U.S.C. 119(b). This foreign priority document was also not found on the WIPO website.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 3/14/06 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there are missing publication titles, year of publication and/or no year of publication listed for some of the non-patent literature references. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims 11 and 12 do not provide any compounds that are identified by the methods described. The compounds identifiable by such method are unknown since they have yet to be identified. Therefore, the compounds of the instant claims are not in the possession of the applicant(s) at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims 11 and 12 do not provide any compounds that are identified by the method described. This is confusing as it is not known what type of compounds would be identifiable by such methods since they have yet to be identified.

6. Claims 11 and 12 are reach through claims, as they do not provide any compounds that are identified by the methods described but attempts to reach into the

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future to encompass compounds that have not yet been identified but would be identifiable by such methods.

### ***Claim Rejections - 35 USC § 102***

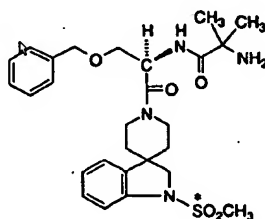
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3,8,9,11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. (WO97/22367).

9. Dean et al. (WO97/22367) teaches of the methanesulfonate salt of the S-35 radiolabeled growth hormone secretagogue, MK0677 (below) (p6, lines 17-25).



The method of identifying a cellular receptor as a growth hormone secretagogue receptor involves contacting the S-35 radiolabeled growth hormone secretagogue with a putative growth hormone secretagogue receptor, such a biological sample/host having growth hormone secretagogue receptor and determining if binding has occurred (p7, lines 3-9). In regards to the method for identifying a compound that can bind to a growth hormone secretagogue receptor, Dean et al. (WO97/22367) teaches of the

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assay to test compounds for their growth hormone secretagogue activity. The assay comprises contacting a compound suspected of being a growth hormone secretagogue with a growth hormone secretagogue receptor, such as a biological sample/host in the presence of the S-35 radioligand and monitoring whether the compound suspected of being a growth hormone secretagogue influences the binding of the S-35 radioligand to the growth hormone secretagogue receptor (p7, lines 10-18). The growth hormone releasing compound of Dean et al. (WO97/22367) would inherently contain at least some of the tritiated methyl product, in a batch of the compound, due to the natural abundance of T (tritium). At least one hydrogen of one of the methyl groups will contain a tritium at that position in a batch of the compound. Claims 1-3 are directed to a radiolabeled growth hormone secretagogue. Since the teachings of Dean et al. (WO97/22367) anticipates the claimed composition, the property of such a claimed composition will be anticipated by the prior art teachings, since the properties, namely the specific activity of radioactively labeled growth hormone secretagogue. The specific activity of the radiolabeled growth hormone secretagogue is a measure of the number of decays per second per amount/concentration of the compound. To increase the specific activity, one would just obtain and/or utilize more of the tritiated compound of Dean et al. (WO97/22367). This does not impart any further limitations on the compound of the instant claims. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to

Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-3,8,9,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (*J. Labelled Compounds and Radiopharm.* **1996**, 28, 561-565) in view of Dean et al. (WO97/22367).

12. Jones et al. (*J. Labelled Compounds and Radiopharm.* **1996**, 28, 561-565) discloses the growth hormone secretagogue MK0677 and that batches of tritium labeled tracer were prepared with high specific activity (up to 1,000 Ci/mmol) and that rapid decomposition of this tritium labeled tracer had not occurred (abstract). Jones et al. (*J. Labelled Compounds and Radiopharm.* **1996**, 28, 561-565) does not disclose the methods of identifying a cellular receptor as a growth hormone secretagogue receptor or the method for identifying a compound that can bind to a growth hormone secretagogue receptor.

13. Dean et al. (WO97/22367) discloses the methanesulfonate salt of the S-35 radiolabeled growth hormone secretagogue, MK0677 and the methods described above.

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14. At the time of the invention it would have been obvious to one ordinarily skilled in the art to recognize that the tritium label found on the tritium labeled MK0677 growth hormone secretagogue of Jones et al. could potentially be substituted at one or more positions of the methyl groups located on the compound. Also, at least one of the hydrogens of the methyl groups, in a batch of the compound, will be substituted with a tritium label due to the natural abundance of tritium. The use of the tritium labeled growth hormone secretagogue MK0677 with the methods disclosed by Dean et al. (WO97/22367) would be obvious since the compounds are identical since, as stated above, at least a portion of a batch of the compound would contain a tritiated hydrogen substituted for one hydrogen on at least one methyl group of MK0677.

15. Claims 1-3,9,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkinen (US 6,548,501B2).

16. Hakkinen (US 6,548,501B2) discloses the tritiated growth hormone secretagogue methanesulfonate salt of MK0677 (column 4, lines 9-11; column 20, lines 28-45; column 21, line 61; column 22, lines 3-5) and the method for identifying a compound as a growth hormone secretagogue. This method from identifying a compound as a growth hormone secretagogue involves treating cells with the subject compound and assaying for activity or binding (column 22, lines 52-67).

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to recognize that the tritium label found on the tritium labeled growth hormone



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secretagogue, MK0677 of Hakkinen (US 6,548,501B2) could potentially be substituted with the tritium at one or more positions of the methyl groups located on the compound.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
December 5, 2006

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER